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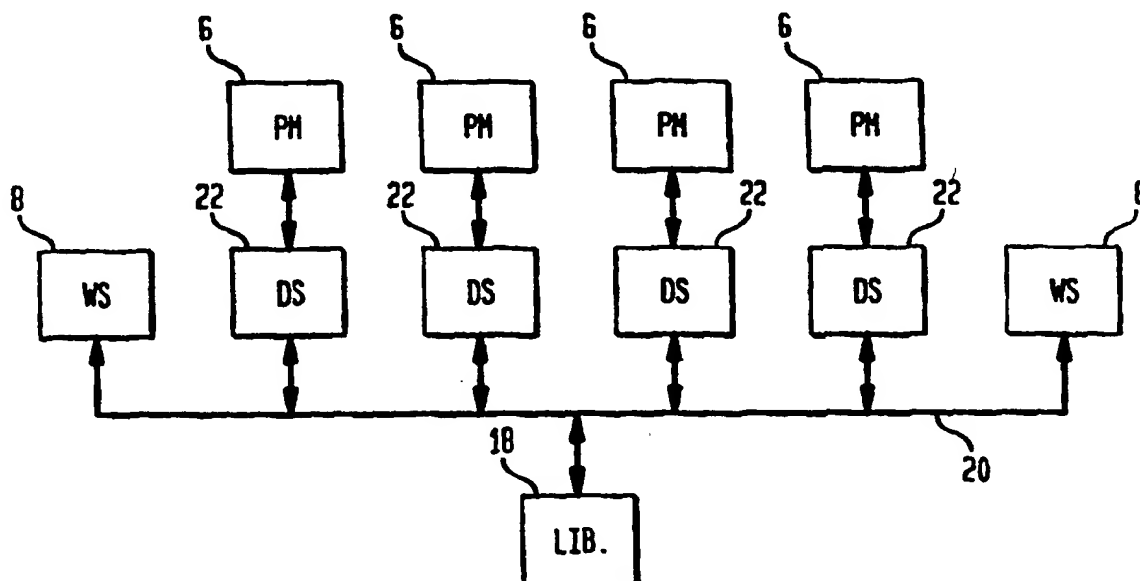
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(54) Title: AUTOMATIC CONFIGURATION OF MEDICAL EQUIPMENT



(57) Abstract

A method and apparatus is provided for automatically configuring the operation of patient-related medical equipment based on the diagnosis and/or care pathway of the patient. A user accessible library of medical equipment titles is provided. Each title comprises a set of instructions which, when selected, are applied via a communication network to at least one of the medical equipments, for automatically configuring its operation based on the diagnosis and/or care pathway of the patient.

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AUTOMATIC CONFIGURATION OF MEDICAL EQUIPMENT

BACKGROUND OF THE INVENTION

5

1. Field of the Invention

The present invention relates generally to medical equipment, and in particular to automatic configuration of the operation of medical equipment.

10

2. Description of the Background Art

Today's medical devices, such as patient physiological monitors, ventilators, etc., are relatively complex, and can literally have thousands of combinations of possible operational configurations, i.e., set-ups and processing programs. Configuration of these devices is typically manually performed by the user, i.e. the clinician, to specifically meet the needs of each patient. Currently, hospitals rely upon the personal clinical knowledge, expertise, of the clinicians to correctly configure the equipment. However, as the patient moves through different stages of care, the optimal configurations are rarely attained or maintained.

It is noted that hospitals are increasingly using a concept called "Care Pathways" (and sometimes referred to as clinical pathways, clinical care pathways and critical care pathways) as standard guidelines to ensure that the patient receives optimal care. Care pathways are treatment plans based on the patient's diagnosis, that change as the patient moves through various stages of care at the hospital. Care pathways can also be different for patients based on differences in their age, sex, or medical problems. Consequently, knowledge of care pathways by the clinician should, and in most case is, also part of the clinicians expertise.

One prior art approach for automatic configuration of medical equipment is described in US patent 5,640,953 entitled PORTABLE PATIENT MONITOR RECONFIGURATION SYSTEM, assigned to the same Assignee as the present invention.

5 A portable patient monitor system is described therein, wherein a plurality of monitor docking stations are located in geographically separate areas of the hospital, each docking station being connected to a common communication network. When a monitored patient is moved
10 from one area to another, it is disconnected from a docking station in the one area and then reconnected to a docking station in the other area. During the move the patient monitor continues to operate, via battery power.

Means are provided in each of the docking stations for
15 automatically adjusting the monitor to an appropriate configuration for the new geographic area upon connection to the other docking station.

Although the technique of US patent 5,640,953 is a
20 great advance over the prior art, further improvement is still desired. For example, the reconfigurations are limited to whatever is preprogrammed for the specific docking station being used. Greater flexibility would be desirable. Additionally, since optimal equipment
25 configurations for the patient's diagnosis and/or care pathway are rarely maintained as the patient progresses through different care units and stages of treatments within those units, it would also be desirable to integrate the concept of care pathways and/or the
30 diagnosis of the patient into the reconfiguration process. Furthermore, the prior art technique only reconfigured portable bedside patient monitors. It would be desirable that other equipments, such as ventilators and anesthesia devices also be automatically
35 reconfigured.

SUMMARY OF THE INVENTION

A method and apparatus is provided for automatically configuring the operation of patient-related medical equipment based on the diagnosis and/or care pathway of the patient. A user accessible library of medical equipment titles is provided, each title comprising a set of instructions which, when selected are applied, via a communication network, to at least one of the medical equipments for automatically configuring its operation based on the diagnosis and/or care pathway of the patient. Two or more of the medical devices may be configured either concurrently or in succession based on the patient's care needs.

More specifically, the library portion of the invention includes a software application that permits the clinician to author the library of medical equipment titles (configurations) that are based on the patient's care pathway and/or diagnosis. These titles can be specific to both the care unit that the patient is in, as well as the patient's diagnosis and/or care pathway (e.g. Coronary Care Unit Acute Myocardial Infarction). The library is connected to a communication network so that the configuration information can be automatically transmitted to the medical device(s). The user can then select the appropriate title at the medical device, which will automatically configure its operation, such as the monitoring (display and processing), alarming, reporting, and notification features of the device.

With the present invention the medical devices become automatically configured components of the hospital's policies and procedures, providing standardized patient care and monitoring functions. Including the patient's diagnosis and/or care pathway in the automatic configuration of the medical devices

provides the medical devices with greater utility and effectiveness in patient care.

Equipment configuration in accordance with the
5 present invention provides the following advantages:

1. automatic configuration of all or some of the patient-dependent user settings
- 10 2. automatic configuration of the alarm scheme (all or some of the alarm settings)
3. automatic reporting and export of relevant patient data
4. automatic analysis of patient data and, if appropriate, notification of the clinician

15

Furthermore, the central library of configurations (titles) can be used throughout the entire hospital. That is, this functionality can be utilized both within a specific care unit in the hospital, such as an Intensive
20 Care Unit, and also for the patient's entire stay in the hospital (as he/she moves from care unit to care unit i.e. from Emergency Room to Surgery to Recovery to Intensive Care to a regular patient room).

25 The invention allows the clinician to simply select the appropriate care pathway and/or diagnosis for the patient from a menu, and the medical device(s) are then automatically configured to optimally meet the patient's needs.

30

The control and standardization of patient care are greatly enhanced when the medical devices are automatically configured according to the established diagnosis or protocols established by the hospital for
35 care pathway-based treatment/monitoring. With the reporting and notification features automatically set, the hospital can centrally control the clinician's

utilization of equipment and the data content being presented to clinicians in specific situations.

BRIEF DESCRIPTION OF THE DRAWINGS

5

Fig. 1 illustrates a prior art monitor configuration technique based on a patient care unit;

Fig. 2 illustrates monitor configuration in accordance with the principles of the present invention;

Fig. 3 illustrates details of the monitor configuration shown in Fig. 2; and

Fig. 4 illustrates monitor configuration in accordance with the principles of the present invention for a coronary artery bypass graft (CABG) patient.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

20

The monitor arrangement of Fig. 1 is illustrative of a prior art patient monitor arrangement in a patient care facility, such as a hospital, constructed and operation in accordance with the forenoted US Patent 5,640,953. Separate intensive care unit (ICU) and operating room (OR) patient monitor systems 2 and 4, respectively, are provided. Each system includes a plurality of portable patient monitors 6 which communicate to a central station (or work station) 8 located in a respective one of care units 2 and 4, via a corresponding one of communication networks 10 and 12. Since monitors 6 are portable, ICU docking stations 14 and OR docking stations 16 are shown for selectively connecting monitors 6 to networks 10 and 12. As previously noted, means are provided in each of docking stations 14 and 16 for automatically adjusting whichever monitor 6 that is connected to it, to an appropriate configuration for that geographic area. The

limitations of such as system were discussed in the background portion of this specification.

Fig. 2 illustrates a technique for configuring the operation of medical equipment (illustratively a patient monitor) in accordance with the principles of the present invention. The structure and operation of the Fig. 2 arrangement is substantially the same as that shown in Fig. 1, but with the following important difference. A user accessible library 18 of medical equipment titles is provided, each title comprising a set of instructions for automatically configuring the operation of at least one monitors 6 based on the diagnosis and/or care pathway of a patient. Since control of monitors 6 is now independent of its particular care unit, different care unit docking stations and communication networks are no longer need. Thus, only a single type of network 20 and docking station 22 are shown. Furthermore, although portable monitors and docking stations are illustrated, in accordance with the present invention portable operation of the monitors, and the use of docking stations, are not required.

Optimal use of the present invention would occur in secondary-level and tertiary-level hospitals. These facilities would provide services that use cardiac monitors, ventilators, cardiac catheterization, and anesthesia equipment. Care units would typically include critical care, surgery, coronary care, burn units, neonatal intensive care, and emergency room services. All of these areas would have access to library 18 (formed by a central network server, either hard-wired or with wireless technology) that would provide each care unit with a library of selections (titles) specific to them. These titles would be based on the patient's diagnosis and/or care pathway.

There are instances when several medical devices are used concurrently, such as in intensive care. In this case, the cardiac patient monitors and the ventilators could use the same titles for their configuration. These
5 devices would also work together to produce unique alarms and reports that combine their data outputs.

Library 18 includes an authoring tool (software), that permits a user to create sets (titles) of equipment
10 configurations. The authoring software includes a user interface that cooperates with library 18, such as its keyboard (not shown) that allows the users to easily create the library of titles useful for automatically configuring the functionality of bedside medical devices,
15 such as cardiac monitors and ventilators. Each of these titles is specific to a care unit and to a patient's care pathway, diagnosis, age, sex, or other determining medical factor. A single title may contain the configurations for one or more medical devices. These
20 titles are saved in a central location in a memory portion of the file server supporting library 18.

The clinician at the bedside can access these titles through a user interface on the medical device. These
25 medical devices are specially programmed to accept these titles via the computer network. The menu of titles for that care unit appears on a display screen of the medical device and the user selects the appropriate title for that patient. For care pathways that are dependent on
30 age, sex, or other factors, the user may have to make two or more selections to access the appropriate title.

TO DO-WORK IN DESCRIPTION FOR FIGURES 3 AND 4

The clinician always has the option of overriding the configurations.
35

These automatic, user-defined functions for physiological monitoring would include:

Set the patient-dependent manual selections
(settings) on the medical devices.

5 This would typically include selections such
as the waveforms, parameters, and trends on
cardiac monitors and central monitor
stations. It would also automatically begin
collection of specific, specialized data in
that medical device. It would also offer
10 suggested settings for pressures and volumes
on a ventilator that would be confirmed by
the user.

Setting the alarm scheme

15 Nearly all medical devices have alarm
settings. In the present invention these
could be tailored to the patient's needs.
Some alarm limits might be set tightly for
some specific titles, while they may be
20 completely disarmed for another. With
multiple devices, combinations of parameters
may be monitored and reported as a single
alarm.

Producing in-unit reports

25 Reports are produced on the laser printer in
the care unit which are used by the
clinicians for communication and/or review.
These reports are customized to report the
data that is relevant and timely for the
30 patient's specific status and problems.
These reports can be tailored to the
individual needs of nurses, managers, and
physicians.

Setting a notification scheme that is tied to pagers
35 and E-mails.

The present invention also includes the
ability to notify different clinicians for

specific events and occurrences. The
authoring tool includes a logic table that is
utilized to analyze conditions for possible
clinician notification. The notification
5 may occur via pager, e-mail, or other
telephony mechanism.

Providing a continuous complication-development risk
rating display

Accessing the logic table again, the user can
10 associate monitored parameters with
complications that are common to the patient
care pathway. This results in either a
continuously updated readout that appears on
a device on the computer network or a link to
15 the notification scheme.

Exporting appropriate data (feedback) to a server,
CIS, or user application

Data exported to other systems and applications
is defined by the user.

20 The frequency, events, data elements, and
export formats are selected by the user with
the authoring tool.

c. Which features are believed to be new?

25 Automatic configuration of physiological monitoring
and medical treatment devices based on the patient
diagnosis and/or care pathway guidelines.

Automatic configuration of physiological monitoring
30 and medical treatment devices based on the care unit and
the patient diagnosis and/or care pathway guidelines.

Use of the clinical pathway patient care concept to
configure and program medical devices via a communication
35 network.

Via a communications network, use of Standard of Care Guidelines for specific diagnoses to automatically configure, program, and update medical devices that are used either concurrently or in succession in the
5 patient's care.

Permitting the clinician to build a library of equipment configuration and function settings (titles) that are based on the patients diagnosis and/or care
10 pathway. The library titles are transmitted over a computer network to medical devices. The user can then select a title that will automatically configure the monitoring, alarm, reporting, and notification features of the device.

15 In accordance with the invention, the library of configurations could also be tied, via an interface, to a Clinical Information System, such as PICIS, which also utilize care pathways in their organization of patient
20 data. Consequently, selecting a care pathway in PICIS would also result in the automatic configuration, via the interface, of the appropriate medical devices to be associated with the patient.

25 Thus, a novel method and apparatus for automatic configuration of the operation of medical equipment has been shown. Many alterations and modifications will become apparent to those of ordinary skill in this art after having read the foregoing description. It is to be
30 understood that the illustrated embodiment is merely exemplary, and is not intended to limit the scope of the following claims. For example, although in the illustrated embodiment medical equipment has been subjected to automatic configuration in accordance with
35 the invention, other types of electronic equipment could be automatically configured. All such variations are intended to be within the scope of the following claims.

CLAIMS

1. Apparatus for automatically configuring the operation
5 of patient-related medical equipment based on the
diagnosis and/or care pathway of the patient, comprising:
- a user accessible library of medical equipment
titles, each title comprising a set that instructions
10 which, when selected are applied to at least one of the
medical equipments for automatically configuring its
operation based on the diagnosis and/or care pathway of
the patient.
- 15 2. The apparatus of claim 1, including an authoring tool
and user interface for allowing a user to prepare the
titles that are selectable.
3. The apparatus of claim 1, further including a
20 communication network coupled for communicating a
selected title between the library and at least one
medical equipment.
4. The apparatus of claim 1, wherein two or more medical
25 devices are configured and programmed concurrently based
on the patient's care needs.
5. The apparatus of claim 1, wherein two or more medical
devices are configured and programmed in succession based
30 on the patient's care needs.

1/2

FIG. 1

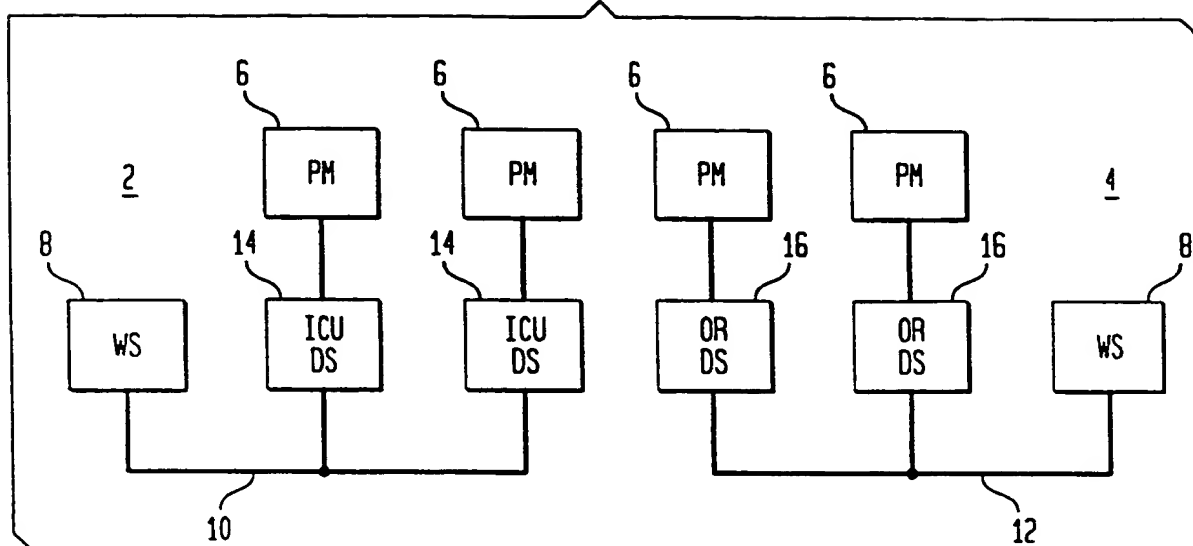
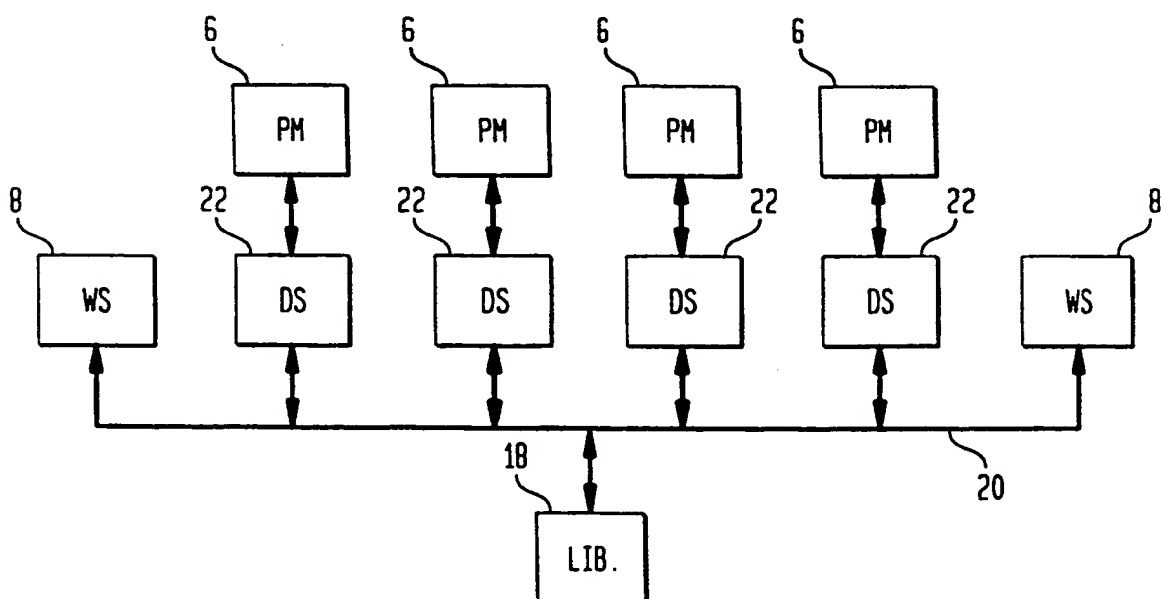


FIG. 2



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FIG. 3

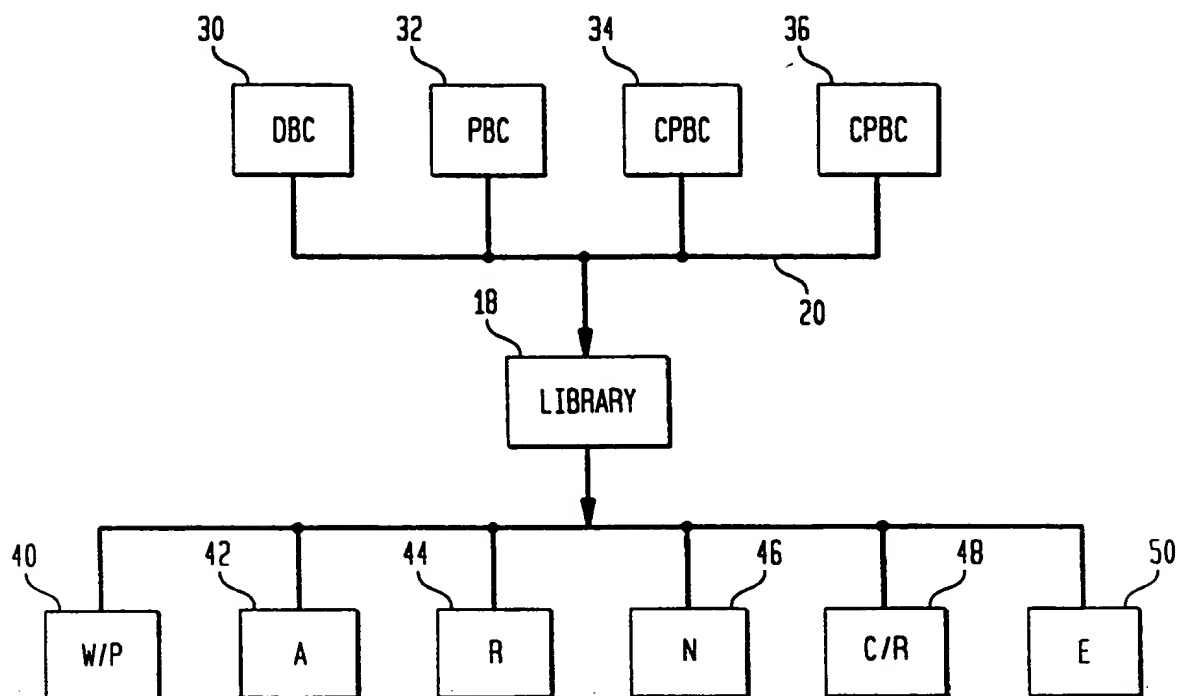
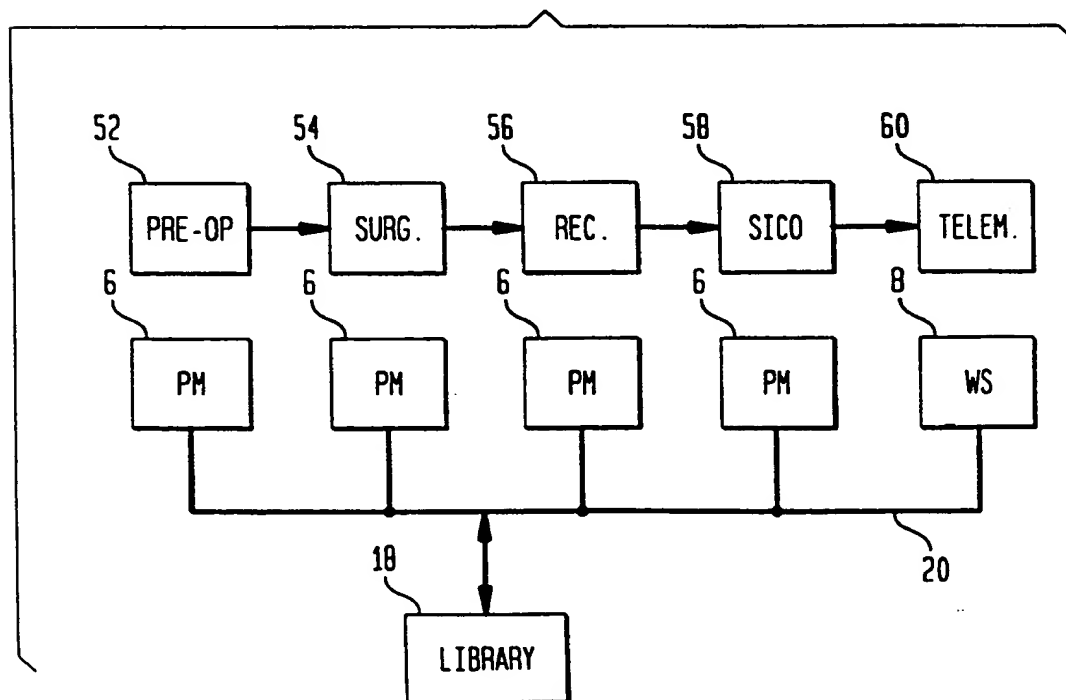


FIG. 4



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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/26620

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 87 05204 A (RODENSTOCK INSTRUMENTE GMBH) 11 September 1987 see page 3, line 17 - page 4, line 1 see page 5, line 18 - page 6, line 27 see page 7, line 12 - line 21 see page 9, line 4 - line 27 ---	1-3
X	WO 96 36923 A (IVAC MEDICAL SYSTEMS, INC.) 21 November 1996 see page 10, line 6 - line 16 see page 12, line 3 - line 28 see page 14, line 20 - line 26 see page 20, line 11 - line 21 see abstract ---	1,3-5
A	---	2
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 24929 A (HEALTHDYNE, INC.) 10 November 1994	1,3
A	see page 5, line 35 - page 7, line 17 see page 8, line 24 - page 9, line 2 ---	2,4,5
X	RICHARD LEVY: "MINICOMPUTER CONTROLS RADIOTHERAPY TREATMENT" ELECTRICAL DESIGN NEWS, vol. 16, no. 20, 15 October 1971, page 17 XP002099710 see the whole document -----	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

I. International Application No

PCT/US 98/26620

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 8705204 A	11-09-1987	DE 3607721 A	10-09-1987
		AT 71826 T	15-02-1992
		AT 71505 T	15-02-1992
		DE 3776042 A	27-02-1992
		DE 3776242 A	05-03-1992
		WO 8705205 A	11-09-1987
		EP 0260286 A	23-03-1988
		EP 0259398 A	16-03-1988
		JP 1500009 T	12-01-1989
		JP 2593085 B	19-03-1997
		JP 63503277 T	02-12-1988
WO 9636923 A	21-11-1996	US 5781442 A	14-07-1998
		CA 2224228 A	21-11-1996
		EP 0846293 A	10-06-1998
		ES 2124678 T	16-02-1999
WO 9424929 A	10-11-1994	US 5558638 A	24-09-1996
		AU 6779194 A	21-11-1994
		EP 0699046 A	06-03-1996